K002996

DEC 11 2000

510(k) Summary

Synergy HA Coated Porous Femoral Stems

Submitter's name:	Smith & Nephew, Inc.
Submitter's address:	1450 Brooks Road, Memphis, TN 38116
Submitter's telephone number:	901-399-6487
Contact person:	David Henley
Date summary prepared:	September 22, 2000
Trade or proprietary device name:	Synergy HA Coated Porous Femoral Stems
Common or usual name:	Prosthetic Hip Joint – HA Coated Porous Femoral Stem
Classification name:	21 CFR 888.3358 hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis-Class II 87LPH

Substantially Equivalent Legally Marketed Devices

- Global Taper Tapered (Synergy) HA Hip Stem - Smith & Nephew
- Secur-Fit® HA Hip Stem – Osteonics® Corp.
- Omnifit® HA Hip Stem – Osteonics® Corp.
- Meridian® ST/PA Femoral Stem – Howmedica Corp.
- APR Porous HA Hip System – Sulzer Orthopedics, Inc.

Device Description

Synergy HA Coated Porous Femoral Stems are manufactured from titanium material (Ti-6Al-4V, ASTM F1472) and are porous coated with bead material manufactured from titanium material (Ti-6Al-4V, ASTM F67, Grade 2, with a mesh size of –45/+60. These stems are designed for use with existing Smith & Nephew cobalt chrome or ceramic modular femoral heads with a 12/14 taper.

Device Intended Use

Total hip components are indicated uncemented use only in individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma, inflammatory joint disease such as rheumatoid arthritis, or non-inflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses such as osteoarthritis; avascular necrosis; traumatic arthritis; slipped capital epiphysis; fused hip; fracture of the pelvis; diastrophic variant; old, remote osteomyelitis with an extended drainage-free period; nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity.

The *Synergy HA Coated Porous Femoral Stem* is designed uncemented use only and for single use only.

Technological characteristics:

Synergy HA Coated Porous Femoral Stems are similar to the legally marketed devices listed above. All of these devices are indicated for total hip replacement, are similar in design to *Synergy HA Coated Porous Femoral Stems*, and have the same technological characteristics.

Performance characteristics:

Data indicate that *Synergy HA Coated Porous Femoral Stems* are substantially equivalent to identified legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 11 2000

Mr. David Henley
Clinical/regulatory Affairs Specialist
Smith & Nephew, Inc.
1450 Brooks Road
Memphis, Tennessee 38116

Re: K002996
Trade Name: Synergy HA Coated Porous Femoral Stems
Regulatory Class: II
Product Code: MEH
Dated: September 22, 2000
Received: September 25, 2000

Dear Mr. Henley:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications Statement

Synergy HA Coated Porous Femoral Stems

Total hip components are indicated for uncemented use only in individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma, inflammatory joint disease such as rheumatoid arthritis, or non-inflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses such as osteoarthritis; avascular necrosis; traumatic arthritis; slipped capital epiphysis; fused hip; fracture of the pelvis; diastrophic variant; old, remote osteomyelitis with an extended drainage-free period; nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity.

for Mark N Milhous

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002996